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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/145,916	09/02/1998	MICHAEL SIMONS	BIS-039	6527

7590

09/24/2002

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EXAMINER

GUZO, DAVID

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 09/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/145,916

Applicant(s)

SIMONS ET AL.

Examiner

David Guzo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 May 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 and 19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☒ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 10 and 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Saunders et al.

Applicants claim a DNA segment comprising DNA sequences encoding an extracellular, transmembrane and cytoplasmic domain of a discrete proteoglycan entity (which can be any syndecan such as syndecan-4) wherein the cytoplasmic domain is from a syndecan-4 molecule and wherein said sequences are joined together. Applicants also claim an expression vector (which can be a plasmid or viral vector) comprising said sequences and endothelial cells which over-express extracellular matrix heparan sulfate proteoglycans at the cell surface, said cells containing the aforementioned expression vector. Applicants also claim a method for making an expression vector comprising positioning a DNA segment encoding a extracellular matrix heparan sulfate proteoglycan (which can be syndecan-4) in an expression vector suitable for expression in endothelial cells.

Saunders et al. (U.S. Patent 5,486,599, issued 1/23/96, see whole document, particularly Columns 2, 6, 21-23, 38-42, Fig. 2 and Tables II-III) recites a DNA segment encoding an entire (or chimeric) syndecan molecule (which can be syndecan-4) and plasmid or viral vectors comprising said syndecan molecule, endothelial cells

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transfected with the vector and capable of expressing the syndecan molecule and a method for making said vector comprising inserting into the vector the sequence encoding the syndecan. Saunders et al. therefore teaches the claimed invention.

Claims 1-2, 4-6 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Stanley et al.

Applicants and Stanley et al. (J. Biol. Chem., Vol. 270, No. 10, 1995, pp. 5077-5083, see whole article, particularly The Abstract, and "Experimental Procedures" section) recite a DNA segment encoding the extracellular, transmembrane and cytoplasmic portions of a discrete proteoglycan entity (which can be a syndecan-4 molecule), a plasmid vector comprising said DNA segment and a method for making said plasmid vector comprising inserting the DNA segment into the vector. It is noted that applicants recite intended use language (i.e. for placement in a suitable expression vector and transfection of endothelial cells) in the DNA segment composition claims and in claim 13. Intended use language in composition claims generally carries no patentable weight since the intended use of the composition does not further limit (absent evidence to the contrary) the nature of the composition itself. With regard to claim 13, applicants recite a method for making an expression vector "intended for transfection of endothelial cells" however, no step in the method recites any feature of the vector which would render it suitable for transfection of endothelial cells. An examination of the specification (pp. 31-32, Table 3) indicates that applicants consider any number of commonly used plasmid vectors are suitable for practicing the instant

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invention and therefore the vector recited by Stanley et al. must be assumed (absent evidence to the contrary) to fall within the vectors contemplated by applicants.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 3, 8-9 and 11 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Applicants recite *in situ* transfected endothelial cells that can be in an *in vivo* environment. The *in vivo* environment can be in a human subject. The claims therefore can be read to include a human being containing the *in situ* transfected cells because the claims read on cells making up a portion of a human being. Claims reading on human beings are non-statutory subject matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, 4-7, 9, 14-17 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-2 (and dependent claims) are vague in the recitation of the term "the syndecan-4 molecule" because there is no antecedent basis in the claims for this

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terminology. Redrafting the claims to recite "a syndecan-4 molecule" would be remedial.

Claim 9 is vague in that the metes and bounds of the claimed subject matter are unclear. It is unclear if applicants are claiming a cell within a subject or the subject itself because the cell is recited as being in an *in vivo* environment and hence cannot be removed from the subject.

Claims 14-17 are vague in that they have not been amended to recite the elected embodiment (stimulating angiogenesis *in situ* in cells *in vitro*). Claim 19 is vague in that it depends from a non-elected claim. Claim 19 must be redrafted to eliminate the dependency from the non-elected claim.

In view of the new grounds of rejection, applicants' arguments filed 7/30/00 are moot.

Any rejections not repeated in this Office Action are withdrawn.

The proposed changes to the Drawings filed 1/16/01 are approved by the examiner.

The Declaration filed 3/5/99 appears to have a non-initialed correction with regard to the spelling of inventor Rudiger Volk's name. It appears that an "e" has been inserted in the first name so that the spelling is Ruediger, but this is not clear.

Clarification is required.

The Sequence Listing filed 2/26/02 has been entered.

No Claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo whose telephone number is (703) 308-1906. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Faxes can be sent to the examiner directly at (703) 746-5061.

Any inquiry of a general nature or relating to the status of this application or proceeding or relating to attachments to this Office Action should be directed to Patent Analyst Zeta Adams whose telephone number is (703) 305-3291.

David Guzo  
May 22, 2002

DAVID GUZO  
PRIMARY EXAMINER  
